

### REMARKS

Claims 1-20 are pending in the application. Claims 15-20 are withdrawn as being directed to non-elected subject matter. Applicants hereby reserve the right to pursue the subject matter of the canceled claims in one or more divisional patent applications.

Claims 1, 2, 6, 10 and 14 have been amended. Claims 1, 2 and 6 have been amended to spell out the acronyms as per the Examiner's objections. Support for the amendments is found throughout the specification. See, for example, page 1, lines 14-16; page 2, lines 9-22; page 7, lines 19-26.

The specification has been amended to correctly identify the trademarks and to correct a typographical error. "IS900" was incorrectly spelt as "ISO900" in some parts of the specification. The error was inadvertent.

No new matter has been introduced by virtue of these amendments and entry is respectfully requested.

Priority under 35 U.S.C. § 119(e) has been acknowledged.

### *Specification*

The disclosure was objected to as the trademarks should have been capitalized. The spelling of FICOLL-ISOPAQUE™ has been corrected.

In view thereof, Applicants respectfully request reconsideration and withdrawal of the instant objection.

### *Claim Objections*

Claim 14 is objected to under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

In response, Applicants have amended claim 14 to indicate that the first pair of primers, as recited in claim 6, consists of P90 and P91.

Claims, 1, 2, 6, and 10 are objected to for reciting acronyms. In response, Applicants have amended the claims to recite the entire names, *Mycobacterium avium* subsp. *paratuberculosis* and polymerase chain reaction, for the acronyms Map and PCR, respectively.

In response, Applicants have amended the claims to provide the correct dependency and spell out the entire name for each acronym. No new matter has been added by virtue of these amendments and entry is respectfully requested. In view thereof, Applicants respectfully request reconsideration and withdrawal of the instant objection.

***Claim Rejections Under 35 U.S.C. § 112***

Claims 1-14 are rejected under 35 U.S.C. § 112, first paragraph. The specification does not enable any person skilled in the art to which it pertains, or with which it is most clearly connected, to use the invention commensurate in scope with these claims.

Applicants respectfully traverse. However, in order to compact and expedite prosecution, Applicants have amended the claims to recite that DNA is extracted. No new matter is added by virtue of these amendments and entry is respectfully requested.

The Examiner alleges that the primers J1 and J2 are not identified in the application. Applicants respectfully traverse. Primers J1 and J2 are identified as SEQ ID NOS: 1 and 2 respectively. See, for example, page 7, lines 19-23. However, to expedite prosecution, Applicants have amended the claims to recite SEQ ID NOS: 1 and 2 instead of J1 and J2.

The Examiner further rejects claims 1-5 for not reciting the 333-bp amplification product. Applicants respectfully traverse. As described in the application, the primers are "nested primers. As such, a nested pair of primers would produce the amplified product indicating

infection with Map. Any one of ordinary skill in the art would recognize that nested primers produce amplified products of a certain size without having to recite the size of the amplification product.

In view thereof, Applicants respectfully request reconsideration and withdrawal of the instant rejection.

Claims 1-14 are rejected under 35 U.S.C. § 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps.

Applicants respectfully traverse. It is clear that Applicants teach detection of Map using primers SEQ ID NOS: 1 and 2 which are nested primers. As is known by one of ordinary skill in the art, a nested primer pair produces an amplification product of a specific size. The information “333 base pair product” is extraneous and not required. Thus one of ordinary skill in the art would know the “metes and bounds” of the instant claim.

Applicants respectfully request reconsideration and withdrawal of the instant rejection.

As to claim 6, Applicants have amended the typographical error (“ISO900”) and replaced it with the correct spelling (“IS900”). The correct spelling is indicated throughout the specification, see, for example, page 2, lines 11-14; page 4, line 1.

As to claim 14, the Examiner alleges that there is insufficient antecedent basis for “the first set or primers.” In response, Applicants have amended claim 14 to provide the proper antecedent basis. No new matter is added by virtue of these amendments and entry is respectfully requested.

The Examiner further asserts that the primers by their designation “J1” and “J2” etc do not provide any structural limitations. Applicants respectfully traverse. However, in order to

expedite prosecution, Applicants have amended the claims to provide structural limitations. "J1" and "J2" are referred to by their sequences. "P90" and "P91" are referred to by the region and size of the sequence generated. Support for this amendment is found, for example, on page 7, lines 19-24. No new matter has been added by virtue of this amendment and entry is respectfully requested.

In view thereof, Applicants respectfully request reconsideration and withdrawal of the instant rejection.

***Claim Rejections Under 35 U.S.C. §§ 102 and 103.***

Claims 1, 3, 6, 7, 8, 9, 11 and 14 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Englund *et al.*, *Diagn. Microbiol. Infect. Dis.* Vol. 33 p. 163-171, 1999.

Applicants respectfully traverse.

In Englund *et al.*, the nucleotide sequence differs from the instant primers J1, J2. The primers in Englund *et al.*, specifically probes for only 210 base pairs in nested PCR which is different to the instant 333 base pairs. Furthermore, these are directed to strain Linda which was isolated from a patient with Crohn's disease and may not reflect bovine field strain MAP seen in cattle. Furthermore, Applicants have amended the claims to indicate the structural information for the instant primers. As such, Englund *et al.*, fails to teach each and every claim limitation of the instant invention.

In view thereof, Applicants respectfully request reconsideration and withdrawal of the instant rejection.

Claims 1, 3, 6, 7, 8, 9, 11 and 14 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Erume *et al.*, *African Health Science* vol. 1 pg. 83-89, 2001.

Applicants respectfully traverse.

The arguments for Erume *et al.* are similar to Englund *et al* whereby there is only a 210 base pair product amplified, and the sequences and alignments differ resulting in detection of less copies of the MAP genome. Furthermore, Applicants have amended the claims to indicate the structural information for the instant primers. As such, Erume *et al.*, fails to teach each and every claim limitation of the instant invention.

In view thereof, Applicants respectfully request reconsideration and withdrawal of the instant rejection.

Claims 1, 3, 4, 5, 6, 7, 8, 9, 11, 12, 13 and 14 are rejected under 35 U.S.C. § 102(a) as being clearly anticipated by Herrewegh *et al.* EP 1223225A1 published July 17, 2002.

Applicants respectfully traverse.

Herrewegh *et al.* conduct only one animal study. The base pair product discussed in Herrewegh *et al.* is extremely low and rather points to a degradation product. As such the primers completely differ as they do not give rise to the same base pair product. Furthermore, Applicants have amended the claims to indicate the structural information for the instant primers. As such, Herrewegh *et al.*, fails to teach each and every claim limitation of the instant invention.

In view thereof, Applicants respectfully request reconsideration and withdrawal of the instant rejection.

Claims 1, 2, 3, 5, 6, 7, 8, 9, 10, 11, 13 and 14 are rejected under 35 U.S.C. § 102(a) as being clearly anticipated by Corti *et al.* BMC Microbiology 2002, 2:15.

Applicants respectfully traverse.

Cortis *et al.* primers are different in sequence and alignment from the instant invention. The primers in Cortis *et al.*, only detect 298 base pairs products different from the 333 base pairs of the instant invention and as such, detect less copies of the MAP genome. Furthermore, Cortis *et al.*, did not determine difference of results when only using primers P90, P91 and then followed by the nested PCR reaction. In addition, the PCR reaction was performed in bulk milk and not on milk obtained from individual animals as in the instant invention. Applicants have amended the claims to indicate the structural information for the instant primers. As such, Cortis *et al.*, fails to teach each and every claim limitation of the instant invention.

In view thereof, Applicants respectfully request reconsideration and withdrawal of the instant rejection.

### CONCLUSION

Applicants respectfully request entry of the foregoing remarks and reconsideration and withdrawal of all rejections. It is respectfully submitted that this application with claims 1-14 define patentable subject matter and is in condition for allowance. Accordingly, Applicant respectfully requests allowance of these claims.

Applicants have made every effort to present claims which distinguish over the cited art, and it is believed that all claims are now in condition for allowance. However, Applicants request that the Examiner call the undersigned (direct line 561-671-3666) if anything further is required by the Examiner prior to issuance of a Notice of Allowance for all claims.


Although, Applicants believe that no further extensions of time are required with submission of this paper, Applicants request that this submission also be considered as a petition for any further extensions of time if necessary. The Commissioner for Patents and Trademarks is hereby authorized to charge the amount due for any retroactive extensions of time and any

In re Application of: BUERGELT, C. D.  
Confirmation No: 3776  
Application No.: 10/802,197  
Examiner: OGUNBIYI, O. A.  
Page - 13 -

deficiency in any fees due with the filing of this paper or credit any overpayment in any fees paid on the filing or during prosecution of this application to Deposit Account No. 50-0951.

Respectfully submitted,  
AKERMAN SENTERFITT

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